4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0248]

Center for Biologics Evaluation and Research eSubmitter Pilot Evaluation Program for Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation to sponsors of investigational new drug (IND) applications to participate in a pilot evaluation program for CBER's eSubmitter Program (eSubmitter). CBER's eSubmitter is a computer-assisted automated program that has been customized to facilitate the creation of IND applications in electronic format, including a template specifically for IND applications related to antivenom drugs/antivenins. Participation in the pilot program is open to sponsors that submit IND applications to the Office of Blood Research and Review, the Office of Cellular, Tissue and Gene Therapy, or the Office of Vaccines Research and Review in CBER. CBER will only accept participation from up to nine sponsors. The pilot program is intended to provide industry and CBER regulatory review staff with an opportunity to evaluate the eSubmitter system and determine if it facilitates the IND submission process. The purpose of this notice is to invite sponsors of IND applications to contact CBER for more information if they are interested in participating in this pilot program.

DATES: Submit an electronic request for participation in this program by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: If you are interested in participating in this program, you should submit an electronic request to CBER_eSubmitter_program@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update the efficiency and quality of its regulatory review process and to facilitate its interaction with stakeholders by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in FDA's development of eSubmitter to improve the process for providing certain regulatory submissions to FDA.

II. eSubmitter Pilot Evaluation Program Expectations

The eSubmitter pilot evaluation program is expected to last approximately 6 months. During this period of time, participants will complete their IND application submissions using the eSubmitter template developed by FDA that has been specifically designed for use by IND sponsors. eSubmitter was developed using the same criteria for applications that are currently used in the IND application review process at CBER. To create the IND application, the participant will enter the requested information into the eSubmitter tool and attach requested documents as an Adobe document (pdf format). This information will be saved onto a CD-ROM by the sponsor and mailed to CBER for review. Paper copies of submissions will not be required. CBER will review the information provided on the CD-ROM and the attachments according to current managed review procedures. Only new IND applications and their amendments will be eligible for participation in the pilot program.

During the IND application process, CBER staff will be available to answer any questions or concerns that may arise. As each application is completed, the users will be asked to comment on the eSubmitter program. These comments and discussions will assist CBER in the final development and release of this electronic program for use by industry.

III. Requests for Participation

Requests to participate in the eSubmitter Pilot Evaluation Program should be sent electronically to CBER_eSubmitter_program@fda.hhs.gov. You should include the following information in your request: Contact name, contact phone number, email address, name of the facility, address, and registration number (if applicable). Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot program.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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